Hegedus et al. Serial No. 09/299,562 Page 4 (New) The pharmaceutical formulation of claim 95, wherein the therapeutically active drug has 103. an aqueous solubility of less than 1x10⁻⁵ M. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active drug has 104. an aqueous solubility of less than $1x10^{-6}$ M. (New) The pharmaceutical composition of claim 95, further comprising an additive 105. from the group consisting of a stabilizer, and a protein aggregation controller. (New) The pharmaceutical composition of claim 95, wherein the molar ratio of the 106. therapeutically active drug to plasma protein is within the range of 1:0.05 to 1:100. (New) The pharmaceutical composition of claim 95, wherein the molar ratio of the 107. therapeutically active drug to plasma protein is within the range of 1:0.1 to 1:50. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is 108. derived from a human. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is 109. derived from an animal other than human. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is a 110. natural plasma protein or a recombinant plasma protein. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is 111. selected from the group consisting of human serum albumin, animal serum albumin, recombinant human serum albumin, recombinant animal serum albumin, γ-globulin, and recombinant γ-globulin. (New) The pharmaceutical composition of claim 95, wherein the plasma protein is 112. selected from a group consisting of immunoglubulin, glycoprotein, interferon, interleukin, and recombinant immunoglubulin, glycoprotein, interferon, and interleukin. (New) The pharmaceutical composition of claim 95, wherein the therapeutically active 113. drug is selected from the group consisting of a cytostatic, an antibiotic, a vitamin, an anti-inflammatory, an analgesic, an antiviral, an anticonvulsant, an immunosupressant, an antiepileptic, an anxiolytic, a hynotic, an antifungal agent, an anticoagulant, a lipid peroxidase inhibitor, a coronary vasodilator, an antiarrythmic agent, a cardiotonic, an uricosuric, an antithrombotic, a steroid hormone (progestogen, androgen, testogen)

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wherein R^1 is tertiary butyl-oxy-carboxylic acid amide or benzoyl amide, R^2 is hydrogen or an acyl group.

- 118. (New) The pharmaceutical composition of claim 117, wherein the acyl group is an acetyl group.
- 119. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is paclitaxel.
- 120. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is paclitaxel.
- 121. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is amphothericin B.
- 122. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is amphothericin B.
- 123. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is gemfibrozil.
- 124. (New) The pharmaceutical composition of claim 112, wherein the therapeutically active drug is gemfibrozil.
- 125. (New) The pharmaceutical composition of claim 111, wherein the therapeutically active drug is miconazole.

Hegedus et al. Serial No. 09/299,562 Page 7 (New) The pharmaceutical composition of claim 112, wherein the therapeutically 126. active drug is miconazole. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 127. active drug is propofol. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 128. active drug is propofol. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 129. active drug is tamoxifen. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 130. active drug is tamoxifen. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 131. active drug is ritonavir. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 132. active drug is ritonavir. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 133. active drug is tacrolimus. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 134. active drug is tacrolimus. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 135. active drug is tirilazad. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 136. active drug is tirilazad. (New) The pharmaceutical composition of claim 111, wherein the therapeutically 137. active drug is trioxsalen. (New) The pharmaceutical composition of claim 112, wherein the therapeutically 138. active drug is trioxsalen. (New) The pharmaceutical composition of claim 105, wherein the additive is selected 139.

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from the group consisting of sodium chloride, a buffer, a poly-alcohol and a water-soluble sugar derivative.

140. (New) The pharmaceutical composition of claim 139, wherein the poly-alcohol is selected from the group consisting of glycerol, mannitol, sorbitol, and dulcitol.

Status of the claims:

Claims 30-37, 42-90 and 93-94 are pending.

Applicants respectfully traverse the rejections and request reconsideration and withdrawal of all rejections in view of the Remarks set forth below. It is believed that this amendment does not raise new issues that would require further consideration and search, and also does not present new matter. It is also believed and respectfully submitted that this amendment simply to comply with the 35 U.S.C.§112 requirement expressly set forth in the previous Office actions. Applicants further submit that the amendment places this application in better form for appeal by materially reducing or simplifying the issues for appeal.

REMARKS

Applicants acknowledge the examiner's confirmation that i) claims 1-23 and 38-41 were cancelled; ii) claims 24-29 were withdrawn and iii) claims 91-92 were withdrawn from consideration. Applicants further acknowledge the examiner's withdrawn of the rejections regarding i) claims 1-9 under 35 U.S.C. §102(b) or alternatively, 103(a); and ii) claims 1-10 under 35 U.S.C. §102(e) as being anticipated by Desai.

Rejection of Claims 30-37 Under 35 § U.S.C. 112, First Paragraph

Claims 30-37 stand rejected under 35 U.S.C. § 112 first paragraph as allegedly not providing enablement for composition other than paclitaxel and albumin. New claims 95-102 are now added to replace claims 30-37.